UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/978,217	11/25/97	BENZ	C 02307E-07111

EXAMINER

HM12/0324

TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO CA 94111-3834

ART UNIT	PAPER NUMBER
1642	7

DATE MAILED: 03/24/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days ~~month(s), or~~ thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-8 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

* U.S. GPO: 1996-421-032/40206

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, 71 and 79, drawn to human ESX polynucleotides, classified in class 536, subclass 23.1, for example. Claims 71 and 79 will be examined with Group I to the extent that they read on a recombinant cell and a kit comprising human ESX polynucleotides.

II. Claims 16-27, 71 and 79, drawn to murine ESX polynucleotides, classified in class 536, subclass 23.1, for example. Claims 71 and 79 will be examined with Group II to the extent that they read on a recombinant cell and a kit comprising murine ESX polynucleotides.

III. Claims 28-32, 78 and 79, drawn to human ESX polypeptides, classified in class 530, subclass 324. Claims 78 and 79 will be examined with Group III to the extent that they read on a pharmaceutical composition and a kit comprising human ESX polypeptides.

IV. Claims 33-37, 78 and 79, drawn to murine ESX polypeptides, classified in class 530, subclass 324. Claims 78 and 79 will be examined with Group IV to the extent that they read on a pharmaceutical composition and a kit comprising murine ESX polypeptides.

V. Claims 38-45, 78 and 79, drawn to human anti-ESX antibody, classified in class 530, subclass 387.1. Claims 78 and 79 will be examined with Group V to the extent that they read on a pharmaceutical composition and a kit comprising human ESX antibodies.

VI. Claims 46-56, 61-63, drawn to hybridization-based detection methods, classified in class 435, subclass 6. Claims 46,47,49-54 will be examined with Group VI to the extent that they read on hybridization-based detection methods.

VII. Claims 46, 47,49-54 and 57-60, drawn to antibody-based detection methods, classified in class 435, subclass 7.1. Claims 46,47,49-54 will be examined with Group VII to the extent that they read on antibody-based detection methods.

VIII. Claims 64-68, drawn to methods of inhibiting growth, comprising administering an antisense nucleotide, classified in class 536, subclass 24.5. Claims 64-66 will be examined with Group VIII to the extent that they read on methods of inhibiting growth with anti-sense nucleotides.

IX. Claims 64-65, 69, drawn to methods of inhibiting growth, comprising administering an antibody, classified in class 424, subclass 130.1. Claims 64-65 will be examined with Group IX to the extent that they read on methods of inhibiting growth with antibodies.

X. Claims 64-65, and 70, drawn to methods of inhibiting growth, comprising administering an inactive ESX, classified in class 514, subclass 2, for example.

Claims 64-65 will be examined with Group X to the extent that they read on methods of inhibiting growth with inactive ESX.

XI. Claims 72-76, drawn to transgenic animals, classified in class 800, subclass 13.

XII. Claim 77, drawn to method of determining whether a gene is regulated by an ESX polypeptide, classified in class 435, subclass 6.

XIII. Claim 78, drawn to a pharmaceutical composition of a vector encoding an ESX nucleic acid (gene therapy), classified in class 514, subclass 44. Claim 78 will be examined to the extent that it reads on gene therapy.

XIV. Claim 80, drawn to a method of screening for a therapeutic lead compound, classified in class 436, subclass 6.

XV. Claim 81, drawn to a method for identification of potential therapeutic targets, classified in class 435, subclass 6, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Each of inventions I-V, XI and XV is directed to a separate and distinct product. Each of inventions I-V, XI and XV would be expected to have distinct morphological, functional, chemical and physical properties as evidenced by divergent classification. It is possible to separately manufacture, use and sell the products as claimed. Furthermore, these products are patentable over each other (though they may each be unpatentable because of the prior art). Inventions I and II and III and IV have the same class and subclass designations but inventions I

and III are drawn to human polynucleotides and polypeptides, respectively; and II and IV are drawn to murine polynucleotides and polypeptides, respectively.

Each of inventions VI-X, XII, XIV and XV is directed to a separate and distinct process. Each of the processes are distinct both physically and functionally, require different steps and use different products.

Inventions I or II and VI, VIII, XIV or XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, as the claims are written inventions VI, VIII, XIV and XV are related to either I or II, thus demonstrating that each of these process can use materially different products. In addition, as the claims are written, both products can be used in multiple processes.

Inventions V and VII or IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in at least two materially different processes.

Inventions III or IV and XII, XIV or XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, as the claims are written, inventions XIV and XV are related to either III or IV, thus demonstrating that each of these process can use materially different products. In addition, as the claims are written, both products can be used in multiple processes.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as separate subjects for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive with regard to the literature search.

3. Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and recognized divergent subject matter and because searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Advisory information

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Ms. Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzel, Ph.D. can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

AH

Anne Holleran
Patent Examiner
March 22, 1999

Nancy A Johnson
Primary Examiner